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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,018	02/25/2002	Olga Bandman	PF-0241-2 DIV	8087

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/084,018

Applicant(s)

Bandman et al

Examiner

Robert C. Hayes, Ph.D.

Art Unit

1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 11, 31, 32, 34, 36-45, and 62-66 is/are pending in the application.
- 4a) Of the above, claim(s) 1, 44, and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1, 11, 31, 32, 34, 36-45, and 62-66 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 6) <input type="checkbox"/> Other |

Art Unit:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group II (claims 11, 31, 32, 34 & 36-43) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the methods of Groups IV & VI "could and should be examined together with the product claims from which they depend, per Commissioner's Notice...", and cites *In re Ochaii* and *In re Brouwer*. Applicants then argue that claim 1 "could [also] be examined along with the antibody claims without undue burden on the Examiner". This is not found persuasive because the search and examination for polypeptides is not the same for antibodies, where only 6 amino acids are required to define an epitope that can be used to generate an antibody to a given polypeptide. Second, the antibodies of Group II can be used in materially different methods, such as therapeutic agents for disease states related to serine carboxypeptidase dysfunction, or as agents to detect such disease states. In contrast, the methods of Groups IV & VI require appropriate labeling protocols, which are not required for the products of Group II. Third, the use of antibodies in Groups IV & VI involve entirely different labeling, detection and purifying protocols than those required in the methods of Group II which alternatively requires animals to immunize and/or hybridoma cells not required in the methods of Groups IV & VI. Lastly, in contrast to Applicants' assertions, because none of the claims in elected Group II are allowable, etc., no rejoining of these groups is required; consistent with that held by the courts in *In re Ochaii* and *In re Brouwer*. Therefore, because these groups are

Art Unit:

distinct and separable for the reasons stated, the requirement is still deemed proper and is therefore made FINAL.

Claims 1, 44 & 45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

However, because each of the different recited sequences in base claims 11, 36, 39 & new claims 62-66 are unique, as exemplified by their unique SEQ ID NOs, which therefore define unique epitopes, further restriction of elected Group II is necessitated because the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Ila. Claims 11, 31-32, 34, 36-43, 62, 63 & 65, drawn to isolated antibodies, and fragments thereof, directed against the polypeptide of SEQ ID NO:1, compositions, and methods of producing such antibodies, classified in Class 424, subclass 130.1+.
- Ilb. Claims 11, 31-32, 34, 36-43, 62 & 64, drawn to isolated antibodies, and fragments thereof, directed against the polypeptide of SEQ ID NO:3, compositions, and methods of producing such antibodies, classified in Class 424, subclass 130.1+.

Art Unit:

IIc. Claims 11, 31-32, 34, 36-43, 62 & 66, drawn to isolated antibodies, and fragments thereof, directed against the polypeptide of SEQ ID NO:5, compositions, and methods of producing such antibodies, classified in Class 424, subclass 130.1+.

3. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed proper because these products appear to constitute patently distinct inventions for the following reason:

Groups IIa-c are directed to products that are physically and functionally distinct, as illustrated by the distinct and unique SEQ ID NOs of the polypeptides of SEQ ID NOs: 1, 3 & 5 required to generate the distinct antibodies of Groups IIa-c. These unique sequences/epitopes alternatively require their own search for similar sequences/ epitopes, which further require search for cross-reacting antibodies within the art. It is pointed out that there is a proper distinction between these groups, since each product is not required in order for the other to exist.

Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as illustrated by the unique SEQ ID NOs of the polypeptides required to generate the unique antibodies claimed, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and

Art Unit:

consider each of the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(I).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 305-4623. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.

August 7, 2003

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